



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

2596-164

Date of Issuance:

3/9/16

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 03/09/2018

Name of Pesticide Product:

Hartz Reference #129

Name and Address of Registrant (include ZIP Code):

Lance Hemsarh
 The Hartz Mountain Corporation
 400 Plaza Drive
 Secaucus, NJ 07094

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03
 Invertebrate & Vertebrate Branch 1, Registration Division
 (7505P)

Date:

3/9/16

2. This registration is time-limited and expires 03/09/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-152

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 2596-164.”
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those

claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 12/31/2015

If you have any questions, you may contact Julie Breeden at 703-347-0511 or via email at Breeden.Julie@epa.gov.

Enclosure

Hartz® Reference # 129 [Primary Brand Name not to be used on any product labels. The word Cat will be included in all Alternate Brand Names and be at least 75% of the size of the largest letter in the product name]

Alternate Brand Names (list at end of document)

[Note: For each brand as packaged, a large, clear picture of a cat in the weight range will be on the front panel of the label.]

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....9.70%

OTHER INGREDIENTS 90.30%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for First Aid and additional Precautionary Statements.

NET CONTENTS: 0.051 fl. oz. (1.5 ml), Contains 3 tubes, each 0.017 fl. oz. (0.5 ml)

For use ONLY on CATS and kittens 8 weeks and weighing 3 lbs. or more.

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

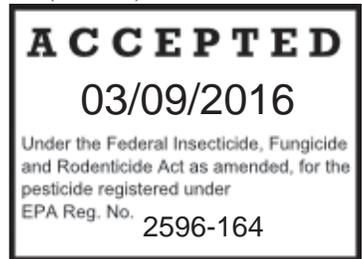
Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or less than 3 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on medicated, debilitated or aged cats. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.



FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.

Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER: Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

TO PREVENT HARM TO YOU AND YOUR CAT READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE.

FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

RESTRICTIONS:

DO NOT APPLY TO CATS UNDER 8 WEEKS OF AGE AND WEIGHING LESS THAN 3 LBS.

DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS.

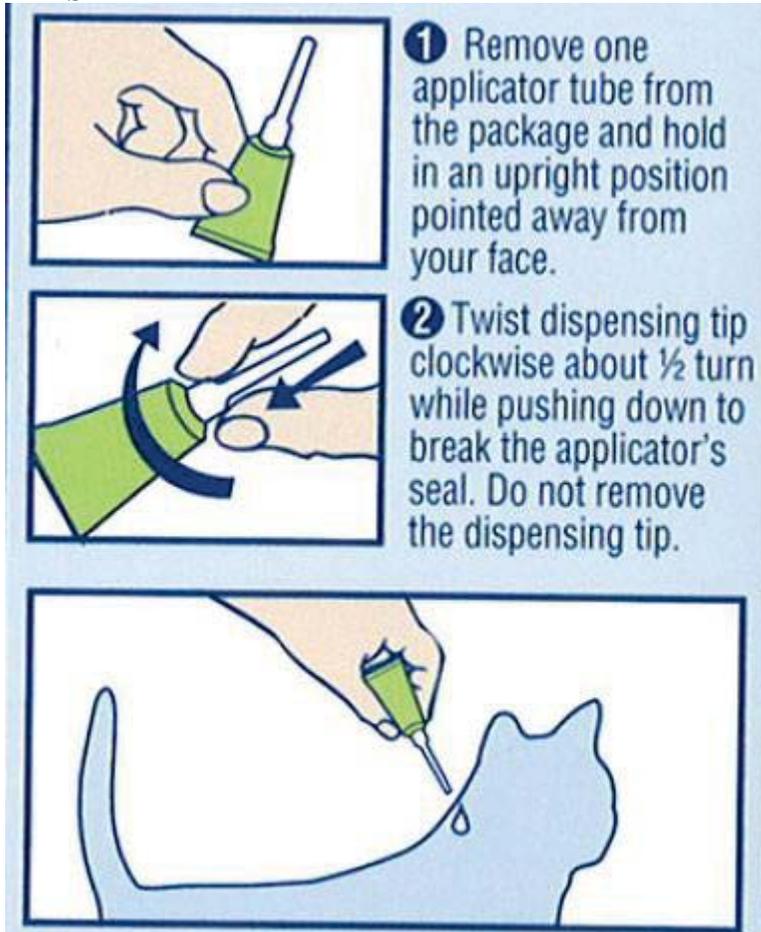
DO NOT EXCEED LABELED DOSAGE AMOUNT FOR CATS.

DO NOT DOUBLE-DOSE OR APPLY MORE THAN ONE APPLICATOR TO CATS.

DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT.

DO NOT ALLOW YOUR CAT TO GROOM ANY OTHER TREATED PETS UNTIL PRODUCT HAS DRIED.

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:



3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Reapply once per month.

SIDE EFFECTS [Located in the lower right hand corner of the back panel]

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE. Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING. Non-refillable container. Do not reuse or refill this container. *If empty:* Place in trash or offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information, call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-164
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)
Made in the U.S.A.

INDIVIDUAL TUBE TEXT

[Product Name]

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5 mL)

Contains fipronil (9.7%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-164

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

FREQUENCY OF APPLICATION

[PRODUCT NAME] kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although [PRODUCT NAME] can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of [PRODUCT NAME] kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

[PRODUCT NAME] remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply [PRODUCT NAME] for 30 days.

[Product Name] can be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

[Product Name] contains Fipronil. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult Fleas

Kills Fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Chewing Lice,

Kills Fleas, Ticks, (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills adult Fleas (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older and weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

MASTER LABEL

Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating queens
Convenient to use
Contains Fipronil. (Product name) effectively targets fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

New (Formula)

Contains Fipronil (, the active ingredients used in Frontline Top Spot®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Top Spot® is a registered trademark of Merial.

Only for use on cats and kittens 8 weeks of age or older weighing 3 lbs or more.
Formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more.

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose
First month, Second month, Third month Value pack
3 month supply
3 monthly treatment(s)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s)
(With) Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is

Applied:

First Dose _____

Second Dose _____

Third Dose _____

Alternate Brand Names [Product names are limited to Alternate Brand Names.

The word Cat will be included in all Alternate Brand Names and be at least 75% of the size of the largest letter in the product name]

Hartz® UltraGuard® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Topical Treatment for Cats (& Kittens)

Hartz® FieldForce™ Topical Treatment for Cats (& Kittens)

Hartz® First Defense™ Topical Treatment for Cats (& Kittens)

Hartz® UltraGuard® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® InControl® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Revo™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® Revo™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® Pro Force™ Topical Solution for Cats (& Kittens)

Hartz® FieldForce™ Topical Solution for Cats (& Kittens)

Hartz® First Defense™ Topical Solution for Cats (& Kittens)

FieldForce™ Topical Treatment for Cats (& Kittens)

First Defense™ Topical Treatment for Cats (& Kittens)

FieldForce™ Topical Solution for Cats (& Kittens)

First Defense™ Topical Solution for Cats (& Kittens)